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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,424	12/20/2001	Thomas W. Leonard	8789-24	3706

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,424	LEONARD ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments with respect to claims 32, 34 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al. (U.S.Patent No. 5,908,638).

Huber et al. teach composition comprising conjugated estrogen composition including (estrone, equilin, 17-alpha-estradiol, 17-alpha-dihydroequilin, 17-beta-dihydroequilin, 17-beta-estradiol, 17-alpha-dihydroequilenin, 17-beta-dihydroequilenin, equilenin, and Δ8,9 Dehydroestrone in combination with progestogen useful for the treatment of per-menopausal, menopausal and post-menopausal disorder in women. (abstract, column 9, TABLE 1). Humber et al. teach postmenopausal women frequently experience a large variety of disorders related to the decrease of estrogen levels in the body such as osteoporosis. (column 1, lines 30-36).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983).

Huber et al. teach composition comprising conjugated estrogen composition including (estrone, equilin, 17-alpha-estradiol, 17-alpha-dihydroequilin, 17-beta-dihydroequilin, 17-beta-estradiol, 17-alpha-dihydroequilenin, 17-beta-dihydroequilenin, equilenin, and Δ8,9 dehydroestrone useful for the treatment of per-menopausal, menopausal and post-menopausal disorder in women. (abstract, column 9, TABLE 1). Humber et al. teach postmenopausal women frequently experience a large variety of disorders related to the decrease of estrogen levels in the body such as osteoporosis. (column 1, lines 30-36).

Huber et al. do not teach the non-aromatizing androgenic compound set forth in claim 32 in a single composition with the conjugated estrogens.

Chesnut et al. teach therapeutic efficacy of stanozolol in postmenopausal osteoporotic women and long-term use of stanozolol may increase the net total bone mass above pretreatment levels. (abstract).

It would have been obvious to one of ordinary skill in the art to combine conjugated estrogen composition taught by Huber et al. with stanozolol in a single composition because the composition comprising conjugated estrogen taught by Huber et al. is useful for the treatment of post-menopausal disorder in woman and because stanozolol is effective for the treatment of postmenopausal osteoporotic women as taught by Chesnut et al. One would have been motivated to make such a modification

in order to achieve at least an additive effect in treatment of postmenopausal disorder, osteoporosis, in a single convenient formulation.

Claims 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al. (U.S.Patent No. 5,908,638) in view of Chesnut et al. (Metabolism Clinical and Experimental, 1983).

Huber et al. teach composition comprising conjugated estrogen composition including (estrone, equilin, 17-alpha-estradiol, 17-alpha-dihydroequilin, 17-beta-dihydroequilin, 17-beta-estradiol, 17-alpha-dihydroequilenin, 17-beta-dihydroequilenin, equilenin, and Δ8,9 dehydroestrone in combination with progestogen useful for the treatment of per-menopausal, menopausal and post-menopausal disorder in women. (abstract, column 9, TABLE 1). Humber et al. teach postmenopausal women frequently experience a large variety of disorders related to the decrease of estrogen levels in the body such as osteoporosis. (column 1, lines 30-36).

Huber et al. do not teach the non-aromatizing androgenic compound set forth in claims 34 in a single composition with the conjugated estrogens and a progestogen.

Chesnut et al. teach therapeutic efficacy of stanozolol in postmenopausal osteoporotic women and long-term use of stanozolol may increase the net total bone mass above pretreatment levels. (abstract).

It would have been obvious to one of ordinary skill in the art to combine conjugated estrogen and progestogen composition taught by Huber et al. with stanozolol in a single composition because the composition comprising conjugated

estrogen taught by Huber et al. is useful for the treatment of post-menopausal disorder in woman and because stanozolol is effective for the treatment of postmenopausal osteoporotic women as taught by Chesnut et al. One would have been motivated to make such a modification in order to achieve at least an additive effect in treatment of postmenopausal disorder, osteoporosis, in a single convenient formulation.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
March 11, 2005